

*aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(iii) *Limitations*. For udder instillation in lactating cattle only. Do not milk for at least 6 hours after treatment; thereafter, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food for 15 days following the latest treatment. If redness, swelling, or abnormal milk persists, discontinue use and consult a veterinarian.

(2) *Dry cows*—(i) *Amount*. 10 milliliters in each quarter at time of drying off.

(ii) *Indications for use*. Treatment of subclinical mastitis caused by susceptible strains of *Staphylococcus aureus* and *Streptococcus agalactiae*.

(iii) *Limitations*. For udder instillation in dry cows only. Do not use less than 30 days prior to calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Treated animals must not be slaughtered for food for 30 days following udder infusion.

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

#### § 526.1810 Pirlimycin.

(a) *Specifications*. Each 10-milliliter syringe contains 50 milligrams (mg) pirlimycin (as pirlimycin hydrochloride).

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.515 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount*. Infuse 50 mg into each infected quarter. Repeat treatment after 24 hours. Daily treatment may be repeated at 24-hour intervals for up to 8 consecutive days.

(2) *Indications for use*. For the treatment of clinical and subclinical mastitis in lactating dairy cattle associated with *Staphylococcus* species such as *Staphylococcus aureus* and *Streptococcus* species such as *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(3) *Limitations*. Milk taken from animals during treatment and for 36 hours

following the last treatment must not be used for food regardless of treatment duration. Following infusion twice at a 24-hour interval, treated animals must not be slaughtered for 9 days. Following any extended duration of therapy (infusion longer than twice at a 24-hour interval, up to 8 consecutive days), animals must not be slaughtered for 21 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 58486, Nov. 2, 1993, as amended at 65 FR 61091, Oct. 16, 2000; 73 FR 811, Jan. 4, 2008]

### PART 528—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 74 FR 6823, Feb. 11, 2009, unless otherwise noted.

#### § 528.1070 Bc6 recombinant deoxyribonucleic acid construct.

(a) *Specifications and indications for use*. Five copies of a human Bc6 recombinant deoxyribonucleic acid (rDNA) construct located at the GTC 155–92 site in a specific hemizygous diploid line of dairy breeds of domestic goats (*Capra aegagrus hircus*) directing the expression of the human gene for antithrombin (which is intended for the treatment of humans) in the mammary gland of goats derived from lineage progenitor 155–92.

(b) *Sponsor*. See No. 042976 in § 510.600 of this chapter.

(c) *Limitations*. Food or feed from GTC–155–92 goats is not permitted in the food or feed supply.

### PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

Sec.

529.40 Albuterol.

529.50 Amikacin sulfate intrauterine solution.

529.400 Chlorhexidine tablets and suspension.

529.469 Competitive exclusion culture.

529.1003 Flurogestone acetate-impregnated vaginal sponge.

529.1030 Formalin.

529.1044 Gentamicin sulfate in certain other dosage forms.